

## **REMARKS**

In the Office Action dated April 8, 2003, claims 15, 3-10, 16-22 and 31-33 were objected to due to informalities specified by the Examiner. All of those informalities have been corrected.

Additionally, claims 15, 3-10 and 31-33 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because the Examiner stated a component or means should be included in claim 15 for determining the distance of the tip from the 2D image plane prior to mixing a designation thereof into the displayed image. Claim 15 has been appropriately amended to include this function as being performed by the mixing unit. All of the claims are therefore submitted to be in full compliance with all provisions of §112, second paragraph.

Claims 15, 3-10 and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Paltieli '029 in view of Ferre et al. '980. Claims 32 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over this combination, further in view of Manwaring et al. '819. Claims 16-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Paltieli '029 in view of Ferre et al. '980 and Cosman '072.

These rejections are respectfully traversed for the following reasons.

As to independent claim 15 and the claims depending therefrom, Applicants submit that the combination of Paltieli '029 and Ferre et al. '980 does not disclose or suggest a mixing unit wherein a designation is mixed into the displayed 2D image that indicates the distance of the tip of the medical instrument from the image plane of the 2D image. The Examiner stated this feature is disclosed in the Ferre et al. '980 reference by Figure 1 and the language at column 5, lines 28-42. The

Examiner further stated that the cross 56 shown in Figure 1 of the Ferre et al. '980 reference as being mixed into the sagittal image 21b and in the axial image 21c is an indication of the distance of the tip of the medical instrument from the image plane presented in the 2D image. Applicants respectfully submit that this interpretation of the images 21b and 21c of Figure 1 of Ferre et al. '980 is not correct.

The crosses 56 mixed into the respective 2D images 21a and 21c in the Ferre et al. '980 reference do not indicate the distance of the tip of an instrument from the plane of the respective 2D image. Instead, the cross 56 designates the position of the tip *within* the plane of each image. This is precisely stated at column 5, lines 21-23 of Ferre et al. '980. The most that is indicated or designated in the images 21b and 21c in the Ferre et al. '980 reference is the distance of the tip of the instrument from the target subject (namely the head, in the example described at this portion of the Ferre et al. '980 reference). There is no indication or designation of the distance of the tip of the instrument from the *image plane* of the 2D image. The images 21b and 21c show only the position of the needle relative to the subject (head), with the needle being located in the image plane but outside of the subject. The distance of the tip of the needle from the image plane itself; therefore, is not specifically indicated in the displayed image, nor can it be concluded from viewing the displayed image.

The subject matter of independent claim 15, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Paltieli '029 and Ferre et al. '980. For the same reasons, none of claims 3-10 nor 31 would have been obvious to a person of ordinary skill in the art based on the teachings of those references, since all of those claims embody the subject matter of claim 15 therein.

Claims 32 and 33 likewise embody the subject matter of claim 15 therein, and therefore even if the Paltieli '029/Ferre et al. '980 combination were further modified in accordance with the teachings of Manwaring et al. '819, the subject matter of claims 32 and 33 still would not have been obvious to a person of ordinary skill in the art under the provisions of 35 U.S.C. §103(a) based on such a combination.

As to independent claim 16, that claim has been amended to state that the image signal acquisition unit is a C-arm X-ray unit, and that the image which is produced by this unit is a 3D image. These amendments are supported in the original disclosure by Figure 4 and the accompanying text beginning at page 13, line 15. Claim 16 is submitted to be patentable over the teachings of Paltieli '029, Ferre et al. '980 and Cosman '072 for the following reasons.

None of the aforementioned references discloses or suggests a system wherein a 3D image dataset is acquired from a subject using a C-arm X-ray device and wherein, in an image of a first subject generated from the 3D image dataset, an image of second movable subject is shown relative to the first subject. None of the Paltieli '029, Ferre et al. '980 or Cosman '072 references discloses or suggests detecting the position of a C-arm X-ray device, the position of a second subject, and the position of the orientation device, using a position detection system. Moreover, none of those references discloses or suggests the use of a mixing unit, supplied with this position information, to cause an image of a movable second subject to be displayed in an image of a first subject.

From a combination of Paltieli '029 and Ferre et al. '980, a person of ordinary skill in the art would be taught only that an image of a medical instrument (in particular, the tip of a medical instrument) can be mixed into an image of a first

subject acquired with an X-ray device. 3D imaging using an X-ray device, and in particular 3D imaging using a C-arm X-ray device, is not disclosed or suggested in Paltieli '029. In connection with the earlier-discussed rejection of claim 15, the Examiner cited column 8, lines 32-63 of Paltieli '029 as teaching an imaging unit that produces a 3D image of a subject from image signals. This passage, however, does not teach the acquisition of a 3D image dataset, but teaches the visualization a three-dimensional image by using a three-dimensional viewing device 170, such as three-dimensional eyeglasses. At lines 38-41 it is stated that three-dimensional images can be formed by displaying consecutive two-dimensional images of an object onto the left and right eyes. This is not the same as acquiring a 3D image dataset and then generating a 3D image therefrom, as set forth in claim 16.

The only relevant teaching in the Cosman '072 reference is to monitor the position of the orientation device with a position detection system, as may be necessary to arrange the patient for radiation therapy. Since the Paltieli '029 and Ferre et al. '980 references are directed to navigation of a medical instrument relative to a patient, Applicants submit that a person of ordinary skill in the art would have no basis to consult the Cosman '072 reference, directed to techniques for positioning the patient himself or herself, in order to modify the devices described in Paltieli '029 and Ferre et al. '980.

Moreover, for the reasons discussed above, even if such a modification were made, for reasons unknown to the present Applicants, a device as set forth in claim 16 still would not result.

Neither Paltieli '029 nor Ferre et al. '980 addresses the problem that, during navigation of an instrument using a 3D image dataset, the generation of which

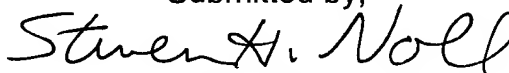
requires a number of 2D X-ray projections to be acquired with an X-ray device, coordinate transformation changes must be identified for mixing an image of the instrument into the image generated from the 3D image dataset after adjustment of the support mechanism for supporting the first subject. In such a case, the 3D image dataset must be newly acquired, without detecting the position of the patient support mechanism, and the coordinate transformation must be newly determined. If the position of the support mechanism were detected, the original coordinate transformation must be modified based only on the determined, changed position of the support mechanism, given an unchanged position of the patient on the support mechanism.

Claim 16 and the claims depending therefrom, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Paltieli '029, Ferre et al. '980 and Cosman '072.

Lastly, an editorial change has been made in claim 4. This change is supported in the specification as originally filed from Figure 2 which shows an ultrasound laparoscope 22, that is also described in the paragraph beginning at page 11, line 12 of the specification as originally filed.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



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